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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,233

06/30/2006

Todd K. Whitehurst

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10/02/2009

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EXAMINER

SO, ELIZABETH K

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

10/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,233	Applicant(s) WHITEHURST ET AL.	
	Examiner ELIZABETH K. SO	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 7-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 19-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/30/2006; 02/13/2008; 05/23/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. As stated in the Response to the Election/Restriction, filed 07/10/2009, applicants elect Group I, containing claims 1-6. Non-elected claims 7-18 have been cancelled and claims 19-26, which depend on claim 1, have been newly added.

Response to Amendment

2. Claims 1-6 are pending in the present application. Non-elected claims 7-18 have been cancelled. New claims 19-26 have been added.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: “20” (see Fig. 5). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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Specification

4. The disclosure is objected to because of the following informalities: the vagus nerve "1148" should be the vagus nerve "148" (see p. 10, lines 25-26).

Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-6 and 19-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Goetz et al (US 7,526,341 B2).

Regarding claims 1 and 19-26, Goetz shows implanting at least one system control unit in a shallow recess of the mastoid area of the skull of a patient (see Fig. 2B and col. 4, lines 58-60); and applying at least one stimulus generated by the system control unit to at least one nerve, thereby at least in part alleviating the symptoms of the epilepsy (see col. 1, lines 34-37); wherein the at least one nerve is selected from at least one of the body, branches of at least one of the vagus nerves, the trigeminal nerves, the ophthalmic nerves, the maxillary nerves, the mandibular nerves, the facial nerves, the glossopharyngeal nerves, and the trigeminal ganglion/ganglia (see col. 3, lines 38-41 and 60-67, where the claimed nerves are either part of or adjacent to the peripheral nerves).

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Regarding claim 2, Goetz shows that the SCU is connected to at least one electrode, and wherein the stimulus comprises electrical stimulation deliverable via the at least one electrode (see col. 3, lines 64-67).

Regarding claims 3-6, Goetz shows that the electrical stimulation decides whether to apply an excitatory or inhibitory stimulation (see cols. 5-6, lines 44-40), or in another embodiment, the SCU is also capable of drug infusion via a catheter/lead as an applicable stimulus option (see col. 3, lines 55-57).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2002/0013612 A1 to Whitehurst discloses an SCU implanted in a surgically-created shallow depression in the temporal bone to provide stimulating drugs and/or electrical stimulation to treat panic disorder, obsessive-compulsive disorder, and other mood and/or anxiety disorders. US 6,129,685 to Howard, III discloses partially implanting an SCU in the mastoid and delivering a therapeutic drug to treat epilepsy.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH K. SO whose telephone number is 571-270-7405. The examiner can normally be reached on Monday - Friday, 10:00 A.M. - 5:00 P.M., EST, and part of the day on Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. K. S./
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit
3766